Laparoscopic Nephrectomy Using the EnSeal Tissue Sealing and Hemostasis System: Successful Therapeutic Application of Nanotechnology

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ABSTRACT

The potential impact of nanotechnology in the field of urology is broad with diagnostic and therapeutic benefits that have only recently begun to be explored. Application of nanotechnology principles to tissue and vessel sealing during laparoscopic procedures may reduce associated thermal injury and inflammatory response. We report our initial experience using the EnSeal Tissue Sealing and Hemostasis System during laparoscopic nephrectomy and discuss its potential advantages and disadvantages compared with those of contemporary technologies.

Key Words: Nanotechnology, EnSeal, Vessel sealing systems, Laparoscopy, Nephrectomy.

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INTRODUCTION

The term nanotechnology describes the application of functional materials, devices, and systems through the control of matter at the nanometer scale.1 The potential uses of nanotechnology are broad, and over the past 5 years urological applications have included body or organ imaging and labeling as adjuncts for diagnosis,2 advanced delivery of therapeutic agents in prostate cancer,3 and bioassays for the detection of prostate-specific antigen.⁴ Recently, the utility of nanotechnology has expanded to include vessel-sealing systems for application during laparoscopic procedures. We describe our experience using the EnSeal Tissue Sealing and Hemostasis System (SurgRx Inc., Redwood City, CA) during laparoscopic nephrectomy and discuss the potential advantages and disadvantages for tissue dissection and vessel sealing that this novel technology affords.

CASE REPORT

An 81-year-old male was referred to our institution for a renal mass incidentally discovered during an abdominal pain workup. Past medical history was significant for hypertension, and he had no previous abdominal surgeries. Computerized tomography scan of the abdomen and pelvis with intravenous contrast (Figure 1) revealed a solid, enhancing, 3-cm lesion in the posterior medial upper pole of the left kidney consistent with renal cell carcinoma. No evidence was present of renal vein invasion or retroperitoneal lymphadenopathy. After extensive discussion regarding surgical approach including cryotherapy and partial nephrectomy, the decision was made to proceed with a laparoscopic left radical nephrectomy.

The patient was placed in the right lateral decubitus position, and 12-mm periumbilical, 12-mm left upper quadrant, and 5-mm superior midline ports were placed using a Veress needle and under direct vision without difficulty. Using the EnSeal, the white line of Toldt was incised, and the descending colon was reflected off of the kidney medially down to the level of the internal inguinal ring. Using the left gonadal vein as a landmark, the left ureter was identified and dissection was continued superiorly to the level of the renal hilum exclusively using the EnSeal

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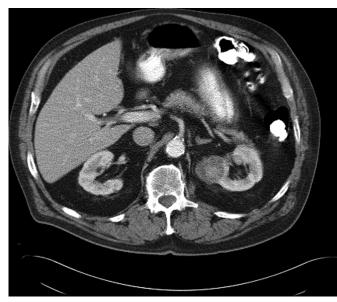


Figure 1. Computerized tomography scan of the abdomen with intravenous contrast revealing a solid, enhancing, 3-cm lesion in the posterior upper pole of the left kidney consistent with renal cell carcinoma.

for both sealing and dividing tissue. The renal vessels were transected after locking polymer Hem-o-lok clips (Teleflex Medical, Research Triangle Park, NC) were applied. Once hilar transaction was complete, the superior and lateral renal attachments were dissected by using the EnSeal. After a clip was placed at the inferior aspect of the left ureter, the ureter was transected, and all remaining medial and inferior attachments were dissected using the EnSeal. The kidney was placed in a 15-mm Endo Catch bag (Tyco Healthcare, Norwalk, CT) and removed through an extended periumbilical incision. The renal fossa was re-examined to ensure adequate hemostasis, and the ports were removed under direct division. Estimated blood loss was negligible (<20 mL).

The patient was discharged with a creatinine of 1.7~mg/dL and a hematocrit of $39.1~\text{x}~10^9$ cells/L on postoperative day 3 after an uncomplicated hospital course. Pathology revealed pT1b clear cell conventional renal cell carcinoma with a papillary growth pattern. At his first follow-up visit, the patient's creatinine was 1.6~mg/dL, and he reported no complaints.

DISCUSSION

With the rapid expansion of laparoscopy in urology, safe and reliable methods of obtaining minimally invasive operative hemostasis are needed. Because traditional methods of controlling bleeding, such as manual pressure, tying, and suture ligation, are not as easily applied in a minimally invasive setting, a heavy reliance on tissue and vessel coagulation is necessary. However, the monopolar, bipolar, and ultrasonic devices currently available for tissue and vessel sealing deliver energy at high temperatures to denature tissue proteins and form a coagulated seal, which can result in unwanted collateral thermal damage, sticking and charring, excessive smoke, and insufficient vessel sealing.^{5,6}

The EnSeal Tissue Sealing and Hemostasis System uses millions of nanometer-sized particles embedded in a bipolar temperature coefficient matrix (Smart Electrode Technology, Figure 2). The cutting mechanism is in the shape of an "I"-beam, utilizing high and equal tissue compression to enhance the seal as the blade is advanced along the length of the jaw (Figure 3). Current flow is only active when the device jaws are closed and is modulated at the tissue-electrode interface by nanoparticles that locally interrupt current flow to tissue when temperatures exceed 100°C. This allows sealing and transection to occur in a single step and simultaneous current regulation minimizing collateral thermal spread and tissue damage. A recent comparison of maximum temperature and thermal spread during vessel sealing between the EnSeal, Gyrus Bipolar Cutting Forceps (ACMI-Gyrus, Maple Grove, MN), Ligasure 5, and SonoSurg Ultrasonic Scissors (Olympus Surgical & Industrial America Inc., Orangeburg, NY) in a porcine model reported that the EnSeal produces mean lower peak temperatures (86.9°C versus 96.9°C to 180°C) and reduced mean thermal spread to surrounding tissues (1.10 mm versus 2.78 mm to 3.23 mm).7 Because tissue temperature is prevented from reaching potentially damaging levels, thermal spread and charring are minimized. Denes et al⁸ evaluated the vessel sealing performance of the EnSeal in a porcine model and reported that the sealed vessel walls are capable of withstanding mean burst pressures greater than 900 mm Hg for vessels less than 7 mm in diameter.

In its closest reported application, the EnSeal has been used to achieve hemostasis of the dorsal venous complex during the robotic-assisted laparoscopic prostatectomy equal to 30 reviewed cases of stapler ligation. In our patient, this technology was used to achieve hemostasis in dissecting and dividing all renal and colonic attachments, including those around the renal hilum. The renal vessels were traditionally divided after application of clips. Estimated blood loss was minimal, and the renal fossa was dry upon final examination. We found that the 5-mm straight jaw EnSeal device proved effective in performing

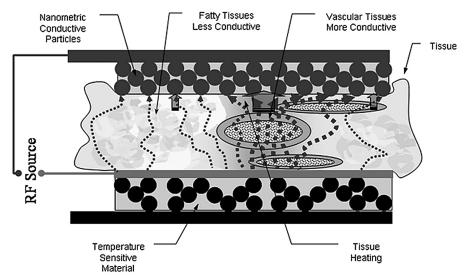


Figure 2. Smart Electrode Technology. Bipolar temperature coefficient matrix. As tissue begins to desiccate, Smart Electrodes on a nanometer scale maintain the conductive path and current flow at a predetermined temperature to provide temperature control and minimize thermal effects.

both blunt dissection and sealing and transection of perirenal tissues (fibroadipose, peritoneal, and lymphatic). With the exception of the hilar vessels, this device proved adequate for sealing and transecting small peripheral vessels less than 3 mm, and subjectively, plume production was minimal compared with previous experiences with the Harmonic ACE (Ethicon Endo-Surgery, Inc., Somerville, NJ) and monopolar cautery devices. We did find that after repeated use, dissection became more arduous due to tissue adherence to the jaws of the device, but recent modifications including a shorter (3 mm) curved jaw may provide some improvement.

CONCLUSION

The potential impact of nanotechnology in the field of urology is wide-ranging with both diagnostic and thera-

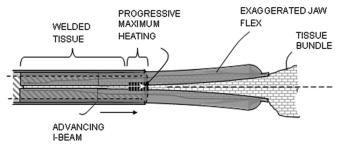


Figure 3. "I" Beam cutting mechanism. The I-beam provides high compression to the treated tissue to enhance tissue seal as the blade is advanced along the length of the jaw. Compression at the apex of the jaw is equal to compression at the distal end.

peutic benefits. The recent application to tissue and vessel sealing during laparoscopic procedures may reduce thermal injury and inflammatory response previously associated with monopolar and bipolar electrocautery. Our initial experience shows that the EnSeal tissue sealing and hemostasis system can be safely utilized during laparoscopic nephrectomy to achieve hemostasis during dissection. Further formal evaluation of vessel-sealing capacity and comparison with known vessel-sealing systems is warranted.

References:

- 1. Shergill IS, Rao A, Arya M, Patel H, Gill IS. Nanotechnology: potential applications in urology. *BJU Int.* 2006;97(2):219–220.
- 2. Harisinghani MG, Barentsz J, Hahn PF, et al. Noninvasive detection of clinically occult lymph-node metastases in prostate cancer. *N Engl J Med.* 2003;348(25):2491–2499.
- 3. Sahoo SK, Ma W, Labhasetwar V. Efficacy of transferrinconjugated paclitaxel-loaded nanoparticles in a murine model of prostate cancer. *Int J Cancer*. 2004;112(2):335–340.
- 4. Wu G, Datar RH, Hansen KM, Thundat T, Cote RJ, Majumdar A. Bioassay of prostate-specific antigen (PSA) using microcantilevers. *Nat Biotechnol*. 2001;19(9):856–860.
- 5. Landman J, Kerbl K, Rehman J, et al. Evaluation of a vessel sealing system, bipolar electrosurgery, harmonic scalpel, titanium clips, endoscopic gastrointestinal anastomosis vascular staples and sutures for arterial and venous ligation in a porcine model. *J Urol.* 2003;169(2):697–700.

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- 6. Diamantis T, Kontos M, Arvelakis A, et al. Comparison of monopolar electrocoagulation, bipolar electrocoagulation, Ultracision, and Ligasure. *Surg Today*. 2006;36(10):908–913.
- 7. Advincula AP, Ko AC, Ganju R, Burke WM, Reynolds RK. Comparison of lateral thermal spread in four electrosurgical devices using real-time thermography. Presented at: Global Congress of Minimally Invasive Gynecology: AAGL 34th Annual Meeting; November 11, 2005; Chicago, Illinois.
- 8. Denes BS, de la Torre RA, Krummel TM, Oleson LM. Evaluation of a vessel sealing system in a porcine model [abstract]. *J Endourol.* 17(suppl 1):1–275, 2003.
- 9. Lee DI, Lee JT, Abrahams HM. Preliminary use of the Enseal™ System for sealing of the dorsal venous complex during robotic-assisted laparoscopic prostatectomy. Abstract presented at: American Urological Association Annual Meeting; May 21–26, 2005; San Antonio, TX.